

REMARKS

After the foregoing Amendment, claims 1 – 30 and 32 – 132 are currently pending in this application. The examiner withdrew claims 79 – 116 and 121 – 132 from consideration in the Action. Claims 1 – 9, 12 – 13, 17 – 19, 22 – 23, 25 – 30, 32 – 33, 37 – 49, 52 – 53, 57 – 59, 62 – 63, 65 – 66, 69 – 78 and 117 – 119 have been amended without prejudice. Claim 31 has been canceled without prejudice. Applicant submits that no new matter has been introduced into the application by the Amendment.

Claim Rejections – 35 USC §112

The Examiner has rejected claims 1 – 79 and 117 – 120 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner has objected to the use of the terms “about”, “approximately”, and “substantially”. Applicant has amended the claims accordingly and requests withdrawal of this rejection.

The Examiner has also rejected claims 1 and 41, and their respective dependent claims, under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner contends that the claim recitation “pH of the liposome composition” makes the claims vague and

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indefinite because the liposomes can have different pH for the aqueous solution encapsulated inside lipid layers than in the aqueous suspension medium for said liposome, and one of skill in the art is unclear as to which of these aqueous portions are being referred to. Applicant has amended the claims to clarify, and requests withdrawal of this rejection.

The Examiner has rejected claims 1 – 5, 41 – 45 and 127 under 35 USC 112, second paragraph, contending that the limitation “the amino group of lipophilic amine” is unclear, for example, when the lipophilic amine has more than one amino group. Applicant submits that a person of skill in the art would understand the scope of the claims. Applicant respectfully traverses, and submits that the claims would be clear to a person of skill in the art, and requests withdrawal of this rejection.

Claim Rejections – 35 USC §102

Camu et al.

The Examiner has rejected claims 1 – 78 and 117 – 120 under 35 USC 102(b) as being anticipated by Camu et al., (US Patent No. 6,149,937). Specifically, the Examiner has stated that Camu discloses a stable liposome composition for delivering a pharmaceutical agent wherein in said liposome is stable and comprises aqueous medium. Camu purportedly also teaches that the pharmaceutical liposome

compositions are prepared by hydrating a film comprising phospholipids including phosphatidyl-choline as well as cholesterol, and that encapsulation is in an aqueous medium at an acidic pH range, wherein the pharmaceutical compounds include lipophilic amines that include anesthetics, morphine and opioids including fentanyl and with pK ranges between 3.5 and 10.5. The Examiner has stated that sterilizing liposome compositions for use as pharmaceuticals or therapeutic purposes is “inherent” in the prior art, and that, therefore, the rejected claims are within the scope of the Camus disclosure.

For a proper anticipation rejection, all of the elements of the claim must be found within a single prior art publication. Camus does not disclose autoclaving the compositions, or autoclaved liposome compositions. Thus, Camus can not anticipate the presently amended claims. Applicant notes that the claim limitations of claim 31 have been incorporated into claim 1 to further clarify this point.

Though the Examiner has not made an obviousness rejection at this time, Applicant respectfully submits that the autoclaving of a liposome composition was, before the filing of the present application, largely thought to significantly degrade liposomally encapsulated drug, and hence the invention of a stable, autoclaved, liposome composition is both novel and unobvious.

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Mezei et al.

The Examiner has rejected claims 1 – 78 and 117 – 120 under 35 USC 102(b) as being anticipated by Mezei et al., (Patent no 5,451,408/US RE38,407E). Specifically, the Examiner contends that Mezei discloses a stable liposome composition for delivering a pharmaceutical agent wherein in said liposome is stable sterile and comprises aqueous medium. The Examiner contends that Mezei further teaches that said pharmaceutical liposome compositions are prepared by hydrating a film comprising phospholipids including phosphatidyl-choline as well as contain sterols, ethanol, and appropriate salts in the encapsulated medium with pH of 7.4, and further encapsulates said pharmaceutical compound in an aqueous medium and suspended in sterile aqueous media, and wherein said pharmaceutical compounds include various lipophilic amines that include anesthetics, morphine, and opioids including fentanyl. Applicant respectfully traverses, and submits that, again, Mezei et al. does not disclose *every* element of any of the current claims. Mezei et al. does not disclose or teach a sterile, stable, autoclaved liposome composition.

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Conclusion

If the Examiner believes that any additional matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to advance the prosecution of this application, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing Amendment and remarks, Applicants respectfully submit that the present application, including claims 1 – 30 and 32 – 132, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

Pliura et al.

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